EXHIBIT N

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DOCKET NUMBER
2483
Office of the Secretary
Int'l Trade Commission

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May 8, 2006

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2006 MAY -8 AM 9:45

VIA HAND DELIVERY

The Honorable Marilyn Abbott
Secretary
U.S. International Trade Commission
500 E Street, S.W.
Washington, DC 20436

NONCONFIDENTIAL VERSION
Confidential Business Information Deleted
On Pages 16 and 17 and In Exhibits J and K

Re: Inv. No. 337-TA-___, *Certain Insulin Delivery Devices, Including Cartridges Having Adaptor Tops, and Components Thereof*

Dear Secretary Abbott:

Enclosed for filing on behalf of Novo Nordisk A/S, Novo Nordisk Inc., and Novo Nordisk Pharmaceuticals Industries, Inc. (collectively, "Complainants"), please find the following documents in support of Complainants' request that the Commission commence an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended. Please note that the Confidential Complaint and Confidential Exhibits J and K to the Confidential Complaint contain Confidential Business Information. Pursuant to the Commission's Rules of Practice and Procedure, a request for confidential treatment of these documents is concurrently transmitted along with this filing. Accordingly, Complainants submit the following:

1. an original and twelve (12) copies of the verified Confidential Complaint and of the nonconfidential Complaint (original and one (1) copy unbound, without tabs (Rules 201.6(c), 201.8(d), and 210.8(a));

2. an original and six (6) copies each of the nonconfidential exhibits, Confidential exhibits, and public version of the Confidential exhibits to the Complaint (original and one (1) copy unbound, without tabs) (Rules 201.6(c), 210.4(f)(3)(i), and 210.8(a));

3. three (3) additional copies of the Confidential Complaint and accompanying Confidential exhibits, and three (3) copies of the nonconfidential Complaint and accompanying nonconfidential exhibits and public version of the confidential exhibits for service upon the three proposed respondents (Rule 210.8(a)) (it is understood that

service of the confidential exhibits will only occur once an administrative protective order has been issued and pursuant to its terms);

4. two (2) additional copies of the nonconfidential Complaint and accompanying nonconfidential exhibits and public version of the confidential exhibits for service upon the Governments of Germany and France (Rule 210.8(a));

5. a certified copy of United States Patent Nos. 5,693,027 (the '027 patent) and a legible copy for each required copy of the complaint (Rule 210.12(a)(9)(i));

6. a certified copy of the assignment of the '027 patent and a legible copy for each required copy of the complaint (Rule 210.12(a)(9)(ii));

7. a certified and three (3) additional copies of the prosecution history of the '027 patent (Rule 210.12(c)(2));

8. four (4) copies of each patent and applicable pages of each technical reference mentioned in the prosecution history of the '027 patent (Rule 210.12(c)(3));

9. physical samples of the domestic products and accused products, including Novo Nordisk's NovoPen® 3, Novo Pen® 3 Demi and NovoPen® Junior, and proposed respondent's OptiClik™ device and Lantus® and Apidra® cartridges, as physical exhibits (Rule 210.12(b)); and

10. A letter and certification pursuant to Commission Rules 201.6(b) and 210.5(d) requesting confidential treatment of the Confidential Complaint and Confidential Exhibits J and K.

Thank you for your attention to this matter.

Respectfully submitted,

Delbert R. Terrill, Jr.
Joanna M. Ritcey-Donohue
Counsel to Complainants

Enclosures

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May 8, 2006

The Honorable Marilyn Abbott
Secretary
U.S. International Trade Commission
500 E Street, S.W.
Washington, DC 20436

Re: Inv. No. 337-TA-___, *Certain Insulin Delivery Devices With Cartridge Adaptor Tops and Components Thereof*

Dear Secretary Abbott:

In accordance with Commission Rules 201.6 and 210.5, Novo Nordisk A/S, Novo Nordisk Inc., and Novo Nordisk Pharmaceuticals Industries, Inc. (collectively "Complainants") request confidential treatment of the Confidential Business Information contained in the Confidential Complaint and Confidential Exhibits J and K to the Confidential Complaint. Information contained in the Confidential Complaint and Confidential Exhibits J and K relates to production, sales, shipments, purchases, or amount or source of income, profits, losses, or expenditures, and other information of commercial value.

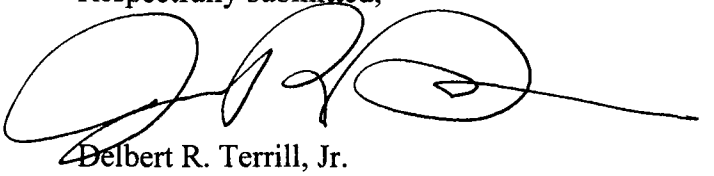
The information described above qualifies as Confidential Business Information pursuant to Rule 201.6(a) in that:

(a) it is not available to the public;

(b) unauthorized disclosure of such information could cause substantial harm to the competitive positions of Complainants; and

(c) unauthorized disclosure of such information could impair the Commission's ability to obtain information necessary to perform its statutory functions.

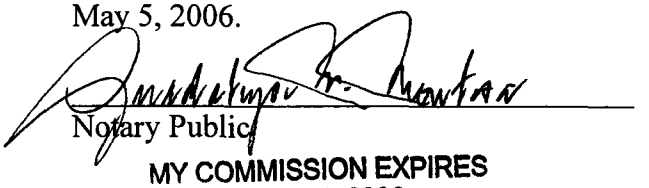
Respectfully submitted,



Delbert R. Terrill, Jr.
Joanna M. Ritcey-Donohue
Counsel for Complainants

District of Columbia

SUBSCRIBED and sworn to before me on May 5, 2006.



Notary Public

MY COMMISSION EXPIRES
JULY 14, 2006

VERIFICATION

I, James C. Shehan, am Vice President/General Counsel of Novo Nordisk Inc. and am duly authorized to sign this complaint on behalf of Novo Nordisk Inc. I have read the complaint and am aware of its contents. To the best of my knowledge, information, and belief, formed after an inquiry reasonable under the circumstances, I hereby certify as follows:

1. The complaint is not being presented for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of the investigation;

2. The claims and other legal contentions in the complaint are warranted by existing law or by a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law; and

3. The allegations and other factual contentions in the complaint have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 5, 2006

James C. Shehan, Vice President/General Counsel
Novo Nordisk Inc.

VERIFICATION

I, Lars Nobert, am General Manager of Novo Nordisk Pharmaceuticals Industries, Inc. and am duly authorized to sign this complaint on behalf of Novo Nordisk Pharmaceuticals Industries, Inc. I have read the complaint and am aware of its contents. To the best of my knowledge, information, and belief, formed after an inquiry reasonable under the circumstances, I hereby certify as follows:

1. The complaint is not being presented for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of the investigation;

2. The claims and other legal contentions in the complaint are warranted by existing law or by a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law; and

3. The allegations and other factual contentions in the complaint have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 5, 2006

Lars Nobert, General Manager
Novo Nordisk Pharmaceuticals Industries, Inc.

NONCONFIDENTIAL VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC

In the Matter of CERTAIN INSULIN DELIVERY DEVICES, INCLUDING CARTRIDGES HAVING ADAPTOR TOPS, AND COMPONENTS THEREOF	Investigation No. 337-TA- ____

COMPLAINT OF NOVO NORDISK A/S, NOVO NORDISK INC., AND NOVO NORDISK PHARMACEUTICALS INDUSTRIES, INC. UNDER SECTION 337 OF THE TARIFF ACT OF 1930

Complainants

Novo Nordisk A/S
Novo Allé
2880 Bagsværd, Denmark
Telephone: 45 4444 8888

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Princeton, New Jersey 08540
Telephone: (609) 987-5800

Novo Nordisk Pharmaceuticals Industries, Inc.
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Clayton, North Carolina 27527
Telephone: (919) 553-6051

Proposed Respondents

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D-65926
Frankfurt am Main, Germany
Telephone: 49 180 22 22 010

Sanofi-Aventis
174/180 Avenue de France
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Bridgewater, New Jersey 08807
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TABLE OF CONTENTS

NONCONFIDENTIAL VERSION

I. INTRODUCTION

1. Complainants Novo Nordisk A/S ("NNAS"), Novo Nordisk Inc. ("NNI") and Novo Nordisk Pharmaceuticals Industries, Inc. ("NNPII") (collectively "Novo Nordisk" or "Complainants") file this Complaint for violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("Section 337") to remedy the unlawful importation into the United States, the sale for importation into the United States, and/or the sale within the United States after importation, and/or the inducement to and/or contribution to the infringement by others, by proposed Respondents Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis, and Aventis Pharmaceuticals, Inc. (collectively "Aventis") regarding certain insulin delivery devices including cartridges with adaptor tops and components thereof (hereinafter "insulin delivery devices") that infringe at least claims 1, 2, 3, 5, 6, 7, 11, 18 and 19 of Novo Nordisk United States Patent No. 5,693,027 (the "'027 patent").

2. Aventis has engaged in unfair acts in violation of Section 337 by infringing, inducing others to infringe, and contributing to the infringement by others of the '027 patent through the importation into the United States, sale for importation, and/or sale within the United States after importation of insulin delivery devices under the name OptiClik™ and cartridges for use with the OptiClik™ device.

3. An industry as required by Section 337(a)(2) and (3) exists in the United States relating to insulin delivery devices (e.g., the NovoPen® 3), including cartridges having adaptor tops, made by Novo Nordisk and protected by the '027 patent.

4. Novo Nordisk seeks a limited exclusion order pursuant to Section 337(d) permanently excluding from entry into the United States Respondents' insulin delivery devices

NONCONFIDENTIAL VERSION

that infringe at least claims 1, 2, 3, 5, 6, 7, 11, 18 and 19 of the '027 patent. Novo Nordisk also seeks an order from the United States International Trade Commission ("Commission") directing Respondents to cease and desist from importing, marketing, offering for sale, or selling OptiClik™ devices and cartridges for use with the OptiClik™ device, including any such devices or cartridges for use with the OptiClik™ device in inventory in the United States ("U.S."), that infringe at least claims 1, 2, 3, 5, 6, 7, 11, 18 and 19 of the '027 patent.

II. PARTIES

A. Complainants

5. Complainant Novo Nordisk A/S ("NNAS") is a corporation organized and existing under the laws of Denmark, with offices located at Novo Allé, 2880 Bagsværd, Denmark. NNAS is the assignee of all right, title, and interest in the '027 patent. NNAS is a healthcare company that is a world leader in diabetes care. In particular, NNAS has been the industry leader in insulin delivery devices ever since the launch in 1985 of NovoPen®, the first pen insulin delivery device. Since 1997, Novo Nordisk has marketed and distributed in the U.S. the NovoPen® 3 and its accompanying cartridges, which together are a Novo Nordisk insulin delivery device embodying claims of the '027 patent.

6. Complainant Novo Nordisk Inc. ("NNI") is a corporation organized and existing under the laws of Delaware. NNI maintains its principal place of business at 100 College Road West, Princeton, New Jersey. NNI is a United States affiliate of NNAS that includes not only its New Jersey headquarters but other U.S. facilities, including Novo Nordisk Research U.S., located in North Brunswick, New Jersey, and a sales network throughout the United States. NNI is Novo Nordisk's North American headquarters, and its operations include, among other things, regulatory, medical, sales, marketing, quality assurance, and distribution work in support of,

among other products, the Novo Nordisk 3 mL PenFill® insulin cartridges and components thereof, including activities that were necessary to bring the Novo Nordisk 3 mL PenFill® insulin cartridges to market. NNI also directs the United States sales force that sells, among other things, Novo Nordisk's 3 mL PenFill® insulin cartridges.

7. Complainant Novo Nordisk Pharmaceuticals Industries, Inc. ("NNPII") is a corporation organized and existing under the laws of Delaware. NNPII maintains its principal place of business at 3612 Powhatan Road, Clayton, North Carolina. NNPII is another United States affiliate which operates a manufacturing facility in Clayton, North Carolina, that has more than 380 employees and supplies insulin cartridges with adaptor tops that utilize the patent at issue, as well as other insulin products, to the U.S. and global diabetes markets.

8. Pursuant to Rule 210.12(a)(9) of the Commission's Rules of Practice and Procedure, a certified copy of United States Patent No. 5,693,027 ("the '027 patent") is appended to this Complaint as Attachment 1. A certified copy of the assignment of rights in the '027 patent from the inventors to Novo Nordisk A/S is attached to this Complaint as Exhibit S.

B. Respondents

9. Respondent Sanofi-Aventis is a corporation organized under the laws of France with a principal place of business at 174/180 Avenue de France, Paris, Cedex 75013 France.

10. Respondent Sanofi-Aventis Deutschland GmbH ("Sanofi-Aventis DG") has a place of business at Industriepark Hoechst, D-65926 Frankfurt am Main, Germany, and is related to Sanofi-Aventis.

11. Respondent Aventis Pharmaceuticals Inc. ("Aventis PI") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 300

NONCONFIDENTIAL VERSION

Somerset Corporate Boulevard, Bridgewater, New Jersey 08807, and is related to Sanofi-Aventis.

12. Upon information and belief, and as described in greater particularity below in Section VII, Sanofi-Aventis and Sanofi-Aventis DG manufacture, and/or have manufactured, import into the United States and/or sell for importation into the United States the OptiClik™ device and components thereof. The OptiClik™ device includes and is for use with both Lantus® (insulin glargine [DNA origin]) ("Lantus®") and Apidra® (insulin glulisine [DNA origin]) ("Apidra®") insulin cartridges.

13. Upon information and belief, and as described in greater particularity below in Section VII, Aventis Pharmaceuticals Inc. distributes, sells, offers to sell, markets, imports into and/or sells within the United States after importation the OptiClik™ device and Lantus® and Apidra® cartridges for use with the OptiClik™ device.

14. Upon information and belief, and as described in greater particularity below in Section VII, Sanofi-Aventis, Sanofi-Aventis DG and Aventis Pharmaceuticals Inc. act in concert to manufacture (and/or have manufactured), import into the United States, sell, offer for sale and/or distribute in the United States the OptiClik™ device and Lantus® and Apidra® cartridges for use with the OptiClik™ device.

III. BACKGROUND INFORMATION ON PRODUCTS AT ISSUE

15. Novo Nordisk has long been a pioneer and innovator in the field of diabetes treatment. It launched the world's first insulin preparation identical to human insulin, the first pen delivery device for delivering insulin, the first pre-filled insulin syringe, the first insulin

doser with a built-in electronic memory, and pioneered the first rapid-acting insulin analog, among many other innovations for treating diabetes.

16. As already stated, the products at issue in this case are insulin delivery devices, including cartridges having adaptor tops, and components thereof. Since 1997, Novo Nordisk has marketed and distributed in the United States its NovoPen® 3 insulin delivery device. When assembled, the NovoPen® 3 includes a durable dosage component, a disposable insulin cartridge, a needle (or syringe) hub that allows the insertion of a needle, and an adaptor top (also disposable) for receiving the cartridge, and the needle hub. The adaptor top ensures that Novo Nordisk cartridges designed specifically for use in the NovoPen® 3 device are compatible with the NovoPen® 3. Because insulin cartridges have different shapes and dimensions, depending on the manufacturer, it is important to couple the insulin cartridge with a delivery device designed for use with that cartridge. Novo Nordisk has, since 2002, also marketed, sold, and/or distributed in the United States NovoPen® Junior and the NovoPen® 3 Demi, which also incorporate the features of the NovoPen® 3 described above. Accompanying this Complaint as Physical Exhibits 1 through 3, respectively, are the NovoPen® 3, NovoPen® 3 Demi, and the NovoPen® Junior devices.

17. NovoPen® 3 can be used with a number of different Novo Nordisk insulin preparations. Specifically, it can be used with human insulins (e.g., Novo Nordisk's Novolin®) and analog insulins (e.g., Novo Nordisk's NovoLog® and NovoLog® Mix 70/30). These insulin products are provided to patients in disposable cartridges called PenFill® cartridges. The PenFill® cartridges are supplied with the adaptor top for adapting and connecting the cartridge to the exchangeable needle hub that allows the attachment of a needle. Designed to grip the insulin cartridge, the adaptor top is also formed to be received by, and to engage with, the durable

NONCONFIDENTIAL VERSION

dosage component of NovoPen® 3. The Novo Nordisk adaptor tops are color-coded. Specifically: Novolin® insulin is provided in a PenFill® cartridge with an adaptor top having a light grey color; NovoLog® Mix 70/30 (Biphasic Insulin Aspart) with an adaptor top having a blue color; and NovoLog® (Insulin Aspart) with an adaptor top having an orange color. The colors allow a patient to readily identify and select for use the type of insulin product in the cartridge. Accompanying this Complaint as Physical Exhibits 4 and 5, respectively, are the Novolin® N and NovoLog® Mix 70/30 insulin cartridges.

18. In 2005, Aventis launched its OptiClik™ device in the United States. OptiClik™ is an insulin delivery device that includes a durable dosage component, a disposable insulin cartridge needle hub and an adaptor top for connecting the cartridge to the exchangeable needle hub and for compatibility of the cartridge with the durable dosage component. Accompanying this Complaint as Physical Exhibit 6 is an OptiClik™ device.

19. In its 2005 launch in the United States, the OptiClik™ device was only marketed for use with Lantus®, a long-acting insulin preparation. The Lantus® cartridges were, and continue to be, manufactured and sold with an adaptor top having a lavender color in the form of an annular ring for identifying the insulin as Lantus®. In February 2006, Aventis launched in the United States Apidra® cartridges for use with the OptiClik™ device. Apidra® is a fast-acting insulin preparation. The Apidra® cartridges have an adaptor top that has a green and a blue color in the form of a longitudinal stripe. An OptiClik™ device, therefore, is now available for use with both Lantus® and Apidra® cartridges in the United States. Both the Lantus® and Apidra® cartridges are fitted with an adaptor top that encompasses the cartridge and provides a connection for connecting the cartridge to an exchangeable needle hub. Accompanying this

Complaint as Physical Exhibits 7 and 8, respectively, are Lantus® and Apidra® insulin cartridges.

20. Therefore, like Novo Nordisk eight years earlier, Aventis has introduced an insulin delivery device that includes a durable dosing portion and a disposable portion. The disposable portion includes an insulin cartridge and has an adaptor top that provides a connection between the insulin cartridge and the exchangeable needle hub. The adaptor top also provides compatibility between the insulin cartridge and the durable dosing portion. Aventis, also like Novo Nordisk before it, has recently introduced multiple types of insulin cartridges for use with its insulin delivery device, each with an adaptor top having a respective identifying color.

IV. THE PATENT AT ISSUE

21. U.S. Patent No. 5,693,027 (the "'027 patent") entitled "Adaptor Top" issued to NNAS as sole assignee on December 2 ,1997 from U.S. Serial No. 313,651, filed September 26, 1994, which claims priority to a series of applications starting with U.S. Serial No. 768,684 (PCT/DK91/00282), filed September 20, 1991, which further claims priority to two Danish applications dated September 21, 1990 and May 16, 1991. The inventors of the '027 patent are Ib Hansen, Søren Mikkelsen and Frits Frydendal Bonnichsen, all of Denmark.

22. Pursuant to Rule 210.12(c) of the Commission's Rules of Practice and Procedure, this Complaint is accompanied by one certified and three additional copies of the prosecution history of the '027 patent, as well as copies of each technical reference mentioned in the file history.

23. The following foreign patents correspond to the '027 patent: EPO Patent No. 549,694; Belgium Patent No. 549,694; Switzerland Patent No. 549,694; Denmark Patent No.

549,694; Spain Patent No. 549,694; France Patent No. 549,694; United Kingdom Patent No. 549,694; Italy Patent No. 549,694; Luxembourg Patent No. 549,694; Netherlands Patent No. 549,694; Sweden Patent No. 549,694; Austria Patent No. 123,418; Germany Patent No. 69110290.2; Greece Patent No. 3,016,997; Japan Patent Nos. 3,042,710, 3,389,045, and 1,131,867; and U.S.S.R. Patent No. 2,068,273.

24. The following foreign patent applications (not already issued as patents) correspond to the '027 patent: Japan Application Nos. 2000-321389 and 4-14563; Denmark Application Nos. 1990 02282/90 and 1991 00926/91; and PCT Application No. PCT/DK91/00282. Of these applications, only the Japanese applications are pending. No other foreign patents or patent applications corresponding to the '027 patent have been filed, abandoned, withdrawn, or rejected.

25. NNAS, assignee of the '027 patent, has granted an implied license under the '027 patent to the Novo Nordisk family of companies, which includes Complainants NNI and NNPII. No other licenses exist under the '027 patent.

V. NON-TECHNICAL DESCRIPTION OF THE INVENTION OF THE '027 PATENT

26. Pen insulin delivery devices were developed by Novo Nordisk as a more convenient and efficient means for the treatment of diabetes than was available with the use of conventional vials and syringes. Standard, disposable cartridges were developed for use with the pen insulin delivery devices. The invention of the '027 patent relates to an adaptor top that conforms the standard cartridge to a particular insulin pen delivery device and to the needle mounting hub of a needle assembly.

NONCONFIDENTIAL VERSION

27. A standard insulin cartridge has a needle or bottleneck end with a rubber membrane pierceable by a needle. The membrane is secured to the bottleneck end by a metal cap. As different pen insulin delivery devices were developed, standardized cartridges were also developed to coordinate with the pen delivery devices. Novo Nordisk was the first to recognize the need in the field of pen insulin delivery devices to adapt standard cartridges for use with needle hubs and with housings of particular devices.

28. The invention of the '027 patent also provides an adaptor top that allows a standard cartridge to be adapted to different insulin delivery devices. An adaptor top can be designed for a particular insulin delivery device. Moreover, insulin cartridges have historically been, and to this day are, made of glass, an unforgiving medium that is difficult to form into particular shapes to accommodate particular pen insulin delivery devices.

29. The adaptor top may include a color code system in which each adaptor top includes a color that indicates the contents of the cartridge. When the color of the adaptor top is visible to the insulin user, the user is reminded of the type of medicine in the cartridge. This color-coded adaptor concept is particularly valuable to a company that is providing multiple insulin preparations for use in a particular insulin delivery device.

VI. UNFAIR ACTS OF RESPONDENTS

30. Pursuant to Commission Rule 210.12(b), the original of this Complaint is accompanied by true and correct copies of the Respondents' OptiClik™ device packaging and product literature, attached as Exhibits A and B. A true and correct copy of the Lantus® package insert discussing the use of Lantus® in the OptiClik™ device is attached as Exhibit C to this Complaint, and a true and correct copy of the Apidra® package insert discussing the use of Apidra® in the OptiClik™ device is attached as Exhibit D to this Complaint. Also

accompanying this Complaint as Physical Exhibits 6, 7 and 8 are an OptiClik™ device, and Lantus® and Apidra® insulin cartridges, respectively.

A. Direct Infringement

1. Respondent Sanofi-Aventis Deutschland GmbH

31. On information and belief, Sanofi-Aventis DG manufactures in part (and has manufactured by Ypsomed AG, a Swiss entity), imports into the United States and/or sells for importation into the United States the OptiClik™ device and components thereof for use in the OptiClik™ device, including Lantus® and Apidra® insulin cartridges. These OptiClik™ devices, cartridges and/or components for use with the OptiClik™ devices, and their distribution, directly infringe at least claims 1, 2, 3, 5, 6, 7 and 11 of the '027 patent, which are directed to pen syringe assemblies. Sanofi-Aventis DG also directly infringes claims 18 and 19 of the '027 patent, which are directed to methods of supplying first and second medicaments, by supplying both Lantus® and Apidra® cartridges in the United States.

32. A claim chart demonstrating how the OptiClik™ device and components thereof infringe exemplary claims 1 and 18 of the '027 patent is attached as Exhibit E.

2. Respondent Sanofi-Aventis

33. On information and belief, Respondent Sanofi-Aventis, in conjunction with Sanofi-Aventis DG and Aventis PI, imports into the United States and/or sells for importation into the United States the OptiClik™ device and components thereof for use in the OptiClik™ device, including Lantus® and Apidra® insulin cartridges. These OptiClik™ devices, cartridges and/or components for use with the OptiClik™ devices directly infringe at least claims 1, 2, 3, 5, 6, 7 and 11 of the '027 patent.

NONCONFIDENTIAL VERSION

34. On information and belief, Sanofi-Aventis, in conjunction with Sanofi-Aventis DG and Aventis PI, supplies both Lantus® and Apidra® insulin cartridges in the United States for use with the OptiClik™ device which infringe claims 18 and 19 of the '027 patent, which are directed to methods of supplying first and second medicaments.

3. Respondent Aventis PI

35. On information and belief, Aventis PI imports into the United States, and/or sells following importation into the United States, the OptiClik™ device and components for use in the OptiClik™ device, including Lantus® and Apidra® cartridges. These OptiClik™ devices, cartridges and/or components for use with the OptiClik™ device directly infringe at least claims 1, 2, 3, 5, 6, 7 and 11 of the '027 patent, which are directed to pen syringe assemblies. On information and belief, Aventis PI directly infringes claims 18 and 19 of the '027 patent, which are directed to methods of supplying a first and second medicament, by supplying both Lantus® and Apidra® cartridges into the United States.

B. Induced Infringement

36. On information and belief, Sanofi-Aventis DG, Sanofi-Aventis and Aventis PI actively induce others to infringe at least claims 1, 2, 3, 5, 6, 7, 11, 18 and 19 of the '027 patent. Sanofi-Aventis DG, Sanofi-Aventis and Aventis PI manufacture or have manufactured the OptiClik™ device and Lantus® and Apidra® cartridges for use with the OptiClik™ device outside the United States, which are then imported into the United States for sale or for distribution to U.S. customers that include distributors, pharmacies, hospitals, doctors, health care professionals and patients. Such U.S. customers directly infringe at least claims 1, 2, 3, 5, 6, 7 and 11 of the '027 patent by selling, offering for sale or using OptiClik™ devices and Lantus® and Apidra® cartridges for use with OptiClik™ devices.

NONCONFIDENTIAL VERSION

37. On information and belief, Sanofi-Aventis DG, in conjunction with Sanofi-Aventis and Aventis PI, actively induces infringement by providing package inserts for inclusion in packages of Apidra® and Lantus® cartridges. These package inserts instruct patients on the use of Lantus® and Apidra® cartridges with OptiClik™ devices. Such use infringes at least claims 1, 2, 3, 5, 6, 7 and 11 of the '027 patent.

38. Aventis PI, in conjunction with Sanofi-Aventis DG and Sanofi-Aventis, also actively induces infringement by distributing and providing the OptiClik™ device to U.S. customers with an instruction leaflet, explaining the use of the OptiClik™ device with Lantus® and/or Apidra® cartridges. Such use infringes at least claims 1, 2, 3, 5, 6, 7 and 11 of the '027 patent.

39. On information and belief, Aventis PI, in conjunction with Sanofi-Aventis DG and Sanofi-Aventis, actively induces infringement by providing customer service and consumer information to U.S. customers, including through a U.S. toll free phone number and websites www.opticlik.com, www.lantus.com and www.apidra.com concerning the use of the OptiClik™ device, and Lantus® and Apidra® cartridges for use with the OptiClik™ device. Such use infringes at least claims 1, 2, 3, 5, 6, 7 and 11 of the '027 patent.

40. On information and belief, Aventis PI, in conjunction with Sanofi-Aventis DG and Sanofi-Aventis, actively induces infringement by supplying both Lantus® and Apidra® cartridges for use with the OptiClik™ devices to U.S. suppliers, including distributors, pharmacies, and hospitals who in turn supply both Lantus® and Apidra® cartridges to U.S. customers for use with the OptiClik™ device. Such supply infringes claims 18 and 19 of the '027 patent.

NONCONFIDENTIAL VERSION

41. On information and belief, Sanofi-Aventis DG, Sanofi-Aventis and Aventis PI have knowledge of the '027 patent. On February 28, 2006, Novo Nordisk sent a letter to Aventis Pharma Deutschland GmbH (now Sanofi-Aventis DG) informing it that Sanofi-Aventis may wish to consider the '027 patent with respect to its OptiClik™ insulin delivery device currently being marketed, imported and/or sold in the United States. In light of this letter, Sanofi-Aventis DG, Sanofi-Aventis and Aventis PI knew or had reason to believe that its supply of Lantus® and Apidra® cartridges and instruction of U.S. customers through package inserts, instruction leaflets, customer service phone lines and websites actively induced and/or caused direct infringement of the '027 patent in the United States.

C. Contributory Infringement

42. Sanofi-Aventis DG, Sanofi-Aventis and Aventis PI contributorily infringe at least claims 1, 2, 3, 5, 6, 7, 11, 18 and 19 of the '027 patent.

43. On information and belief, Sanofi-Aventis DG, in conjunction with Sanofi-Aventis and Aventis PI, makes Lantus® and Apidra® cartridges in Germany for use with the OptiClik™ device. The Lantus® and Apidra® cartridges are sold to U.S. customers for use with the OptiClik™ device, which infringes at least claims 1, 2, 3, 5, 6, 7 and 11 of the '027 patent.

44. On information and belief, Sanofi-Aventis DG, Sanofi-Aventis and Aventis PI have knowledge of the '027 patent. On February 28, 2006, Novo Nordisk sent a letter to Aventis Pharma Deutschland GmbH (now Sanofi-Aventis DG) informing it that Sanofi-Aventis may wish to consider the '027 patent with respect to its OptiClik™ insulin delivery device currently being marketed, imported and/or sold in the United States. In light of this letter, Sanofi-Aventis DG, Sanofi-Aventis and Aventis PI knew or had reason to believe that its supply of Lantus® and

NONCONFIDENTIAL VERSION

Apidra® cartridges contributed to and/or caused direct infringement of the '027 patent in the United States.

45. On information and belief, by instructing U.S. customers through package inserts, instruction leaflets, customer service phone lines and websites, Aventis PI, in conjunction with Sanofi-Aventis DG and Sanofi-Aventis, is aware of use by its customers that infringes at least claims 1, 2, 3, 5, 6, 7 and 11 of the '027 patent.

46. Lantus® and Apidra® cartridges are not staples of commerce. The Lantus® and Apidra® cartridges are specifically designed for use with the OptiClik™ device. The Lantus® and Apidra® package inserts state that the "[c]artridge systems are for use only in OptiClik™ (Insulin Delivery Device)." Such use infringes at least claims 1, 2, 3, 5, 6, 7 and 11 of the '027 patent. As such, the Lantus® and Apidra® cartridges have no substantial non-infringing uses.

VII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION

47. Upon information and belief, the OptiClik™ device and Lantus® and Apidra® cartridges for use with the OptiClik® device are imported into the United States and/or sold for importation by Sanofi-Aventis DG in conjunction with Sanofi-Aventis. Upon information and belief, the OptiClik™ device is imported into the United States and/or sold following importation into the United States by Aventis PI. Based on current information and facts available, the Harmonized Tariff Schedule classification for the infringing products – the OptiClik™ device and components for use therewith, including Lantus® and Apidra® cartridges – includes subheadings 3004.31.0000 and 9018.39.0050.

48. As set forth in the accompanying documents, OptiClik™ devices and Lantus® and Apidra® cartridges are imported into the United States for distribution and/or sale in the

NONCONFIDENTIAL VERSION

United States for the treatment of diabetes. Attached as Exhibit C is a true and correct copy of the product insert and labeling for Lantus®, demonstrating the distribution and/or sale of Lantus® cartridges in the United States. Attached as Exhibit D is a true and correct copy of the product insert and labeling for Apidra®, demonstrating the distribution and/or sale of Apidra® cartridges in the United States. These Exhibits contain text indicating that these products are made outside the United States. (See highlighted text in Exhibit C at page 6, and in Exhibit D at page 3.) Also attached as Exhibits A and B are true and correct copies of OptiClik™ device packaging and literature indicating that it is manufactured outside the United States.

49. As further set forth in the Declaration of Marc A. Began attached as Exhibit U, Lantus® and Apidra® cartridges are available for purchase, and have been purchased, after import into the United States for distribution and/or sale in the United States. (The Lantus® and Apidra® cartridges accompanying this Complaint as Physical Exhibits 7 and 8, respectively, are not the same cartridges that are the subject of the Declaration of Marc A. Began attached as Exhibit U.) Upon information and belief, Respondents' OptiClik™ device without insulin cartridges, i.e., the durable portion only, is generally not sold in the U.S. market but rather distributed at no charge to medical doctors for distribution at no charge to their patients.

50. Upon information and belief, attached as Exhibit F is a true and correct copy of a memorandum dated February 1, 2006 from Joe Puma, Director, Trade Operations, Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals Inc., both located in the United States, to "Pharmaceutical Buyer." In the memo, Mr. Puma states that on January 24, 2006, Aventis announced the availability of Apidra vials and further states that Aventis will start shipping Apidra cartridges to pharmaceutical buyers the week of February 6, 2006. Upon information and belief, attached as Exhibit T is a true and correct copy of a memorandum dated January 10, 2005

NONCONFIDENTIAL VERSION

to "Pharmaceutical Buyer" from Tara J. Stevens, Head of Trade Development & Direct Sales, Aventis Pharmaceuticals Inc., announcing the availability of Lantus® 3-mL cartridges for use with the OptiClik™ device.

51. Upon information and belief, Aventis PI markets and provides customer service to customers in the United States through an assortment of websites concerning the use of Lantus® and Apidra® cartridges as part of and in conjunction with the OptiClik™ device. These websites include www.lantus.com (copies of printouts from www.lantus.com are attached as Exhibit G), www.opticlik.com (copies of printouts from www.opticlik.com are attached as Exhibit H) and www.apidra.com (copies of printouts from www.apidra.com are attached as Exhibit I).

VIII. DOMESTIC INDUSTRY

52. NNAS, NNI and NNPII satisfy the domestic industry requirement of 19 U.S.C. Section 1337(a)(2),(3).

A. Significant Investment in Plant and Equipment

53. NNPII was founded in 1989 as a company for producing Novo Nordisk's insulin products in the United States. NNPII is located in Clayton, North Carolina, on more than 260 acres with manufacturing facilities of more than 250,000 square feet. (Declaration of Lars Nobert attached as Exhibit J.) NNPII purchased the location in Clayton, North Carolina, in 1989, and began the process of building manufacturing facilities that comply with both FDA standards for producing insulin products as well as Novo Nordisk standards for producing insulin products of the highest quality and reliability. After extensive testing and validation, in 1995, NNPII started commercially producing commercial insulin products at its North Carolina facility. Today, NNPII manufactures both insulin vials and cartridges, annually producing [

] insulin vials for use with conventional syringes (i.e., not the claimed pen delivery device) and an average of [ ] insulin cartridges, consisting substantially of the Novo Nordisk 3 mL PenFill® insulin cartridges for use with durable pen device systems, but also insulin cartridges used with disposable pen device systems (i.e., not the claimed durable pen delivery device). The Clayton Facility utilizes automated production equipment and machinery to manufacture the Novo Nordisk 3 mL PenFill® insulin cartridges, including machinery to sterilize and fill the cartridges with insulin. (Declaration of Lars Nobert attached as Exhibit J.)

54. In October 2004, Novo Nordisk announced a detailed plan to expand the size and scope of NNPII's Clayton facility, including the creation of 187 new jobs and an investment of $100 million. The first phase of the expansion was completed in January 2006, doubling the insulin-filling capacity of the Clayton facility. Additional expansion is underway that will increase the number of Novo Nordisk products made at Clayton and expand the facility by an additional 130,000 square feet and increase the Clayton Facility's packaging capacity for its Novo Nordisk 3 mL PenFill® insulin cartridges and other products. (Declaration of Lars Nobert attached as Exhibit J.)

B. Significant U.S. Employment of Labor

55. Novo Nordisk significantly employs labor in the United States. NNPII employs 384 employees at its Clayton facility generating a significant payroll of $20.2 million (US), not including benefits, for the 2005 calendar year. These employees have significant responsibility for supervising, operating and maintaining the facility's manufacture of insulin vials and insulin cartridges, including the PenFill® cartridges, for distribution into the United States market and for exportation to overseas markets. (Declaration of Lars Nobert attached as Exhibit J.)

NONCONFIDENTIAL VERSION

56. NNI currently employs 1,860 employees at its headquarters in Princeton, New Jersey and through its sales network located around the United States and thereby generates a significant payroll. These employees have responsibilities for, among other things, regulatory, medical, manufacturing, marketing, quality assurance, and distribution work in support of the PenFill® cartridges, all of which are activities necessary or helpful to bring products covered by the '027 patent to market. NNI also directs the U.S. sales force that sells, among other things, Novo Nordisk's 3 mL PenFill® insulin cartridges. (Declaration of Jeffrey A. Frazier attached as Exhibit K.)

C. Substantial Investment in the Exploitation of the Patented Invention

57. Novo Nordisk has made and continues to increase its substantial investment in exploiting the invention of the '027 patent. (Declaration of Lars Nobert attached as Exhibit J.) NNPII's facility and its manufacture of the Novo Nordisk 3 mL PenFill® insulin cartridges, for use in Novo Nordisk's NovoPen® 3, NovoPen® 3 Demi, and NovoPen® Junior, utilize specialized and technical equipment and processes, on and about which certain of the Clayton Facility's personnel must be trained and proficient, including systems and equipment performance (engineering). Furthermore, NNI provides training to its national sales force and conducts focused educational outreach to the diabetes community. NNI's educational outreach, along with its sales and marketing activities, were and are crucial for the initial and ongoing development of the U.S. market for Novo Nordisk 3 mL PenFill® insulin cartridges, which is crucial to Novo Nordisk's success in the United States for the Novo Nordisk PenFill® insulin cartridges and NovoPen® insulin delivery devices.

NONCONFIDENTIAL VERSION

D. Establishment of a Domestic Industry

58. In the alternative, the activities described above demonstrate that a domestic industry is in the process of being established. As previously stated, NNPII's recent expansion of the Clayton Facility enlarges the Facility's production and packaging capacity for Novo Nordisk's PenFill® insulin cartridges, as well for its other products. The work leading to the recent upgrade of Novo Nordisk's ability to manufacture PenFill® insulin cartridges in the Clayton Facility's expanded facilities at least constitutes an industry in the process of being established.

E. Novo Nordisk Practices the Invention of the '027 Patent

59. As detailed above, NNPII manufactures and ships insulin cartridges for use in, for example, NovoPen® 3, NovoPen® 3 Demi, and NovoPen® Junior devices that embody the '027 patent both for distribution in the United States and for export to other countries. NNI sells, distributes and/or markets, for example, NovoPen® 3, NovoPen® 3 Demi, and NovoPen® Junior devices and insulin cartridges in the United States that embody the '027 patent. Attached as Exhibits L and M are true and correct copies of excerpts of the instruction booklets and packaging for the NovoPen® 3 and the NovoPen® Junior devices, respectively. Attached as Exhibits N, O, P, and Q are true and correct copies of the packaging for the Novolin® N, Novolin® R, NovoLog®, and NovoLog® Mix 70/30 PenFill® insulin cartridges, respectively. In accordance with Rule 210.12(b) of the Commission's Rules of Practice and Procedure, accompanying this Complaint as Physical Exhibits 1 through 3, respectively, are the NovoPen® 3, NovoPen® 3 Demi, and the NovoPen® Junior devices. The Novolin® N and NovoLog® Mix 70/30 insulin cartridges are accompanied herewith, respectively, as Physical Exhibits 4 and 5.

NONCONFIDENTIAL VERSION

60. A claim chart demonstrating that Novo Nordisk's NovoPen® 3 and associated insulin cartridges embody exemplary claims 1 and 18 of the '027 patent is attached as Exhibit R.

IX. OPTICLIK DEVICE IN OTHER PATENT INFRINGEMENT LITIGATION

61. On September 2, 2005, Novo Nordisk A/S sued Sanofi-Aventis, Aventis PI, Sanofi-Aventis DG and Aventis Pharma AG in the U.S. District Court for the District of Delaware for patent infringement of U.S. Patent No. 6,582,408 (the "'408 patent"). On December 2, 2005, Novo Nordisk A/S voluntarily dismissed Aventis Pharma AG and on December 12, 2005, the remaining Aventis defendants answered and counterclaimed for non-infringement and invalidity.

62. Novo Nordisk A/S asserts that the Aventis defendants are infringing the '408 patent by making, using, selling, offering to sell or importing into the United States the OptiClik™ device.

63. The '408 patent litigation in Delaware is in the early stages of fact discovery, which is scheduled to close in October 2006, with a projected trial date of August 13, 2007.

64. The subject matter of this Complaint has been involved in no other existing or past litigation.

X. RELIEF

65. By reason of the foregoing, Novo Nordisk A/S, Novo Nordisk Inc., and Novo Nordisk Pharmaceuticals Industries, Inc. request that the United States International Trade Commission:

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A. Institute an immediate investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. Section 1337, into the violations of Section 337 by Respondents based upon the unlawful importation into the United States, the sale for importation, sale after importation into the United States, the inducement to and/or contribution to the infringement by others regarding, the accused OptiClik™ device and components thereof for use therewith, including Lantus® and Apidra® cartridges;

B. Determine that there has been a violation of Section 337;

C. Issue a limited permanent exclusion order, pursuant to Section 337(d) of the Tariff Act of 1930, as amended, excluding from entry into the United States all devices and components thereof for use therewith that are manufactured by or on behalf of, imported or sold by or on behalf of Sanofi-Aventis DG, Sanofi-Aventis and Aventis PI, their affiliates, subsidiaries, successors, or assigns that infringe one or more claims of United States Patent No. 5,693,027;

D. Issue a permanent cease and desist order pursuant to Section 337(f) of the Tariff Act of 1930, as amended, prohibiting Sanofi-Aventis DG, Sanofi-Aventis, Aventis PI, their affiliates, subsidiaries, successors, or assigns from importing, selling, offering to sell, marketing, distributing, and providing customer service for all devices or components thereof including any devices and/or components thereof in inventory in the United States for use therewith that infringe one or more claims of United States Patent No. 5,693,027; and

NONCONFIDENTIAL VERSION

E. Grant such other and further relief as it deems appropriate under the law based upon the facts complained of herein and as determined by the investigation.

Dated: May 8, 2006

Respectfully submitted,

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Attorneys for Complainants

U.S. Patent 5,693,027

U 1448992

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

April 05, 2006

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THIS OFFICE OF:

U.S. PATENT: *5,693,027*
ISSUE DATE: *December 02, 1997*

By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office

L. Edelen

L. EDELEN
Certifying Officer

US005693027A

United States Patent [19]

Hansen et al.

[11] Patent Number: 5,693,027

[45] Date of Patent: Dec. 2, 1997

[54] **ADAPTOR TOP**

[75] Inventors: **Ib Hansen**, Herlev; **Søren Mikkelsen**, Holte; **Frits Frydendal Bonnichsen**, Lynge, all of Denmark

[73] Assignee: **Novo Nordisk A/S**, Bagsvaerd, Denmark

[21] Appl. No.: 313,651

[22] Filed: Sep. 26, 1994

Related U.S. Application Data

[63] Continuation of Ser. No. 53,503, Apr. 27, 1993, abandoned, which is a continuation of Ser. No. 768,684, filed as PCT/DK91/00282, Sep. 20, 1991, published as WO92/04926, Apr. 2, 1992, abandoned.

[30] **Foreign Application Priority Data**

Sep. 21, 1990 [DK] Denmark 2282/90
May 16, 1991 [DK] Denmark 926/91

[51] Int. Cl.[6] A61M 5/00

[52] U.S. Cl. 604/232; 604/200; 604/51

[58] Field of Search ..... 604/232, 240–242, 604/200, 201, 905, 415, 181, 51; 215/324, DIG. 3

[56] **References Cited**

U.S. PATENT DOCUMENTS

Re. 31,873	4/1985	Howes	128/674
31,873	4/1861	Howes	128/674
Re. 31,878	5/1985	Howes	128/674
1,594,493	8/1926	Brown	604/232
2,020,828	11/1935	Goldberg	604/201
2,818,864	1/1958	Hudson	604/415
2,865,372	12/1958	Miskel et al. .	
3,130,724	4/1964	Higgins et al.	604/201
3,130,742	4/1964	Higgins et al.	604/201
3,336,924	8/1967	Sarnoff et al.	604/415
3,375,825	4/1968	Keller	604/201
3,820,652	6/1974	Thackston	604/201 X
3,895,633	7/1975	Bertner et al.	604/232 X
3,916,893	11/1975	De Felice .	
3,989,044	11/1976	Meierhoefer	604/243 X
4,089,432	5/1978	Crankshaw et al.	604/415 X
4,490,142	12/1984	Silvern	604/241
4,664,656	5/1987	Taddei	604/241
4,740,205	4/1988	Seltzer	604/192
4,768,568	9/1988	Fournier et al.	604/905 X
4,781,701	11/1988	Gepträgs	604/240
4,944,736	7/1990	Holtz	604/403
4,948,000	8/1990	Grobenkort	215/DIG. 3 X
5,205,833	4/1993	Harsh et al.	604/240

FOREIGN PATENT DOCUMENTS

2 137 405	2/1973	Germany .	
0315980	10/1969	Switzerland	604/201
0501411	2/1971	Switzerland .	
501 411	2/1971	Switzerland .	
1205021	9/1970	United Kingdom	604/200
1 437 595	5/1976	United Kingdom .	
1 525 455	9/1978	United Kingdom .	
WO 89/02760	4/1989	WIPO .	

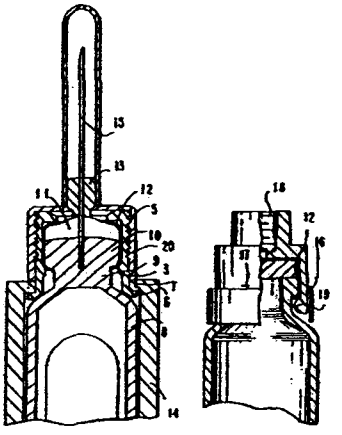
Primary Examiner—Michael Powell Buiz
Assistant Examiner—A. T. Nguyen
Attorney, Agent, or Firm—Steve T. Zelson, Esq.; James J. Harrington, Esq.

[57] **ABSTRACT**

A plastic top for adapting to a chosen syringe (14) a standard cartridge (8) of the kind having a neck (9) with a flange (10) and being closed by a rubber membrane (11) sealingly secured against the flange (10) by a metal cover (12) having its edge beaded behind the flange. This plastic top has a bore (2) for receiving the neck part (9) of the cartridge (8), which bore (2) has a diameter making it fit over the metal cover (12) and is provided with protrusions (3;9) gripping behind the edge of the metal cover (12) when the neck part (9) is inserted in the bore. The outer contour of the plastic top is adapted to the syringe type in which the cartridge is going to be used.

The plastic top is provided with a thread (5;18) coaxial with the bore to receive a needle hub (13) in a way making its needle (15) penetrate the membrane (11) of the cartridge (8) when the hub (13) is mounted on the thread (5) of the plastic top.

19 Claims, 3 Drawing Sheets



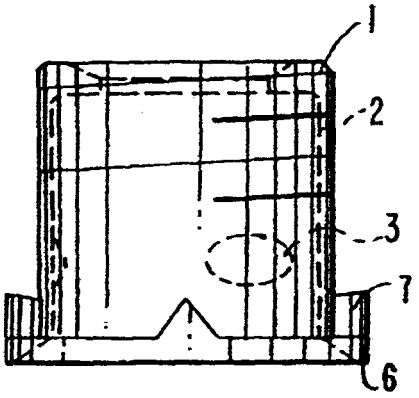


FIG. 1

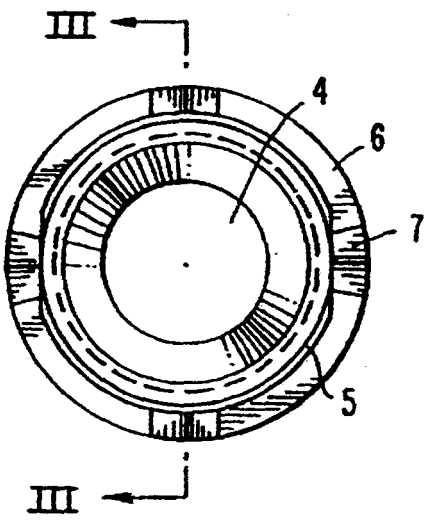


FIG. 2

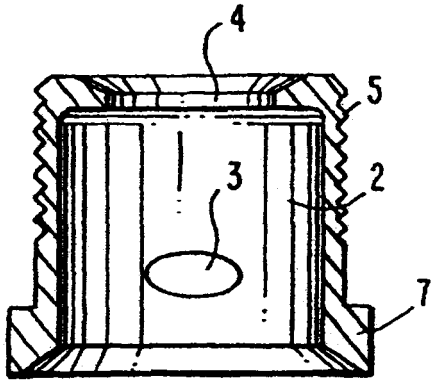


FIG. 3

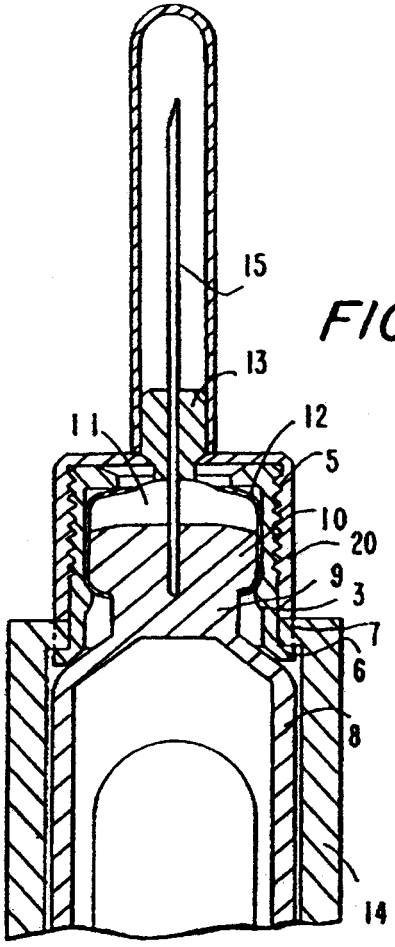


FIG. 4

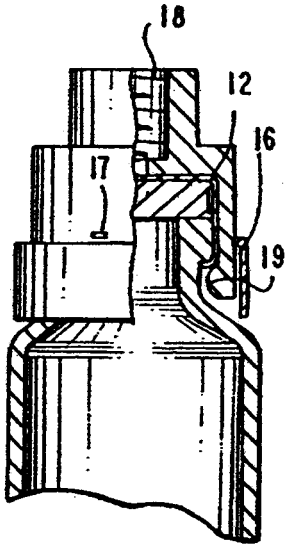


FIG. 5

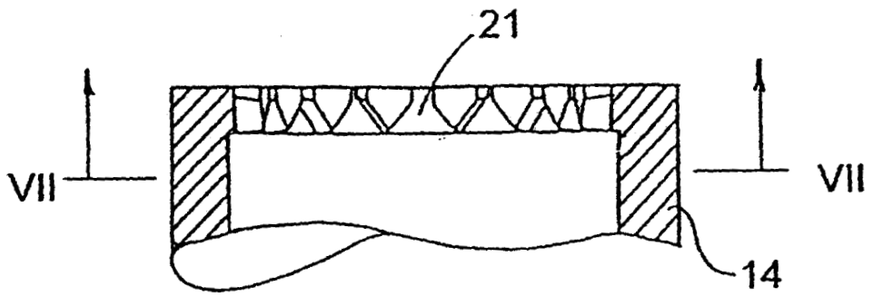


Fig. 6

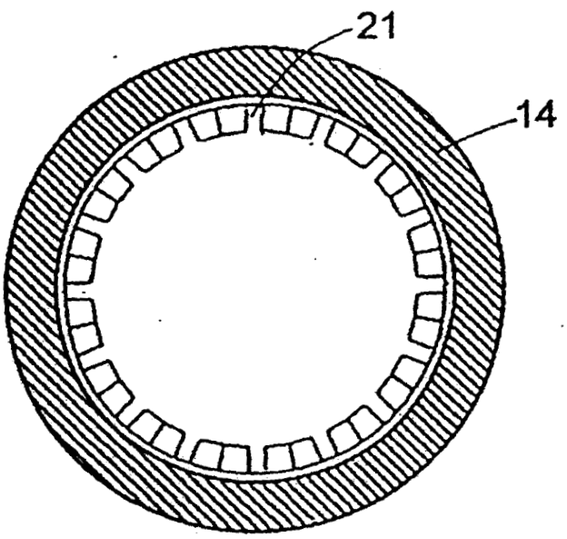


Fig. 7

ADAPTOR TOP

This application is a continuation application of co-pending application Ser. No. 08/053,503, filed on Apr. 27, 1993, abandoned, which is a continuation of application Ser. No. 07/768,684 filed as PCT/DK91/00282 Sep. 20, 1991 published as WO92/04926 Apr. 2, 1992, the contents of which are incorporated herein by reference now abandoned.

The invention relates to ampules for pen syringes. Such ampoules are commonly shaped as a glass tube being at one end closed by a piston, which may be pressed into the tube to expel the content of the tube at the other end of the tube. This other end is formed as a bottle neck, the outer end of which is closed by a rubber membrane, which may be pierced by an injection needle through which the content is expelled.

DESCRIPTION OF THE RELATED ART

In a standard cartridge the outer end of the bottleneck is provided with an external flange supporting the rubber membrane, and this membrane is sealingly secured over the opening of the neck against the flange by a metal cap having a central opening exposing the central part of the membrane over the opening of the neck, having side walls extending along the sides of the membrane and the flange, and having its end beaded to grip under the lower side of the flange.

As new types of pen syringes were developed the cartridges or at least the neck thereof was given different shapes to accommodate these types of syringes. The use of plastic closures instead of the standard metal cap has made it necessary to design the flanges for cooperation with such plastic tops which demand a greater accuracy of the glass flange if a reliable sealing shall be obtained. Consequently, the different insulin types each have to be marketed in different types of cartridges whereby the manufacturing and the stockpiling is made complicated.

SUMMARY OF THE INVENTION

It is the object of the invention to provide a system of tops making a standard cartridge usable in an optional pen.

This is obtained by a plastic top which according to the invention has a bore for receiving the neck part of the cartridge, the bore having a diameter fitting over the metal cover, the inner wall of the bore being provided with protrusions for gripping behind the edge of the metal cover when the neck part is inserted into the bore, and the outer contour of the top being formed to adapt the chosen syringe type.

By using such a plastic top only one type of cartridges has to be manufactured as the adaption to a chosen type of syringe is made by the choice of plastic top. This means that the department filling the cartridges will not have to dispose of different filling machines or to rearrange existing machines to fill different types of cartridges with the same type of medicine. The mounting of the plastic top need not take place under sterile conditions as do the filling, and as the plastic top is of no importance to the sealing of the cartridges, the high accuracy demand may be reduced as the protrusions in the bore only have to secure the plastic top so that it cannot easily be removed, but do not have to prevent rotation or small axial movements of the plastic top on the neck part.

According to the invention the plastic top may be provided with a thread coaxial with the bore to receive a threaded needle hub carrying a double pointed needle, the thread of the top being provided so that when the needle hub is screwed onto the top mounted on a cartridge the one pointed end of the needle will penetrate the rubber membrane of the cartridge. This way the plastic top may serve the same purpose as do the known plastic closures.

The plastic top may be provided with means for keyed engagement with corresponding means in a syringe to keep it unrotable when mounted with a cartridge in the syringe. This is of importance when a needle should be screwed onto the top. In some types of syringes such keyed engagement between cartridge and syringe is further used to ensure that only a certain type of cartridge is used in the syringe.

According to the invention the top may be made from a coloured plastic in accordance with a colour code system for the content of the cartridges. Such a colour code system exists for insulin preparations revealing if a cartridge contains slow or quick acting insulin or a mixture thereof. Especially where the code top having an external thread is used the user is reminded of the type of medicine in the cartridge each time he has to screw a new needle onto the thread of the plastic top.

The plastic top may surround only the neck part of the cartridge or it may cover a bigger or smaller part of the cartridge and even form a part of the housing of a syringe, which may simplify the changing of cartridges.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in further details with reference to the drawing, wherein

FIG. 1 shows a front view of an embodiment of an adaptor top according to the invention,

FIG. 2 shows a plan view of the embodiment shown in FIG. 1,

FIG. 3 shows a sectional view along the line III—III in FIG. 2,

FIG. 4 shows a cylinder ampoule with an adaptor top as illustrated in FIGS. 1–3 mounted in a pen syringe,

FIG. 5 shows another embodiment of an adaptor top according to the invention.

FIG. 6 is a front, sectional view of the forward end of the pen syringe; and

FIG. 7 is a sectional view of the pen syringe, taken in the direction of the arrows VII—VII of FIG. 6.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

An adaptor top shown in FIG. 1 comprises a body 1 with a bore having a diameter slightly bigger than the diameter of the metal cap of a standard cylinder ampoule. The cylindric inner wall 2 of the bore is provided with protrusions 3 which may grip under the beaded lower edge of the metal cap of a standard ampoule, when the top is fitted with its bore over the closure of the ampoule. In the shown embodiment there are three protrusions with an angular spacing of 120°, but more protrusions or a single ring shaped protrusion may be used just as the scope of the invention is not deviated from by using two or one protrusion.

The protrusions 3 are given a height ensuring a good grip under the edge of the metal cap and the top is mounted by pressing the top with its bore over the metal cap making the protrusion pass the cap by the plastic material of the top being incidentally deformed. The protrusions 3 are placed in the bore of the body 1 in a position making them reach their gripping position under the edge of the metal cap before the

insertion of the ampoule neck part into the bore is stopped by the top of the closure abutting the bottom of the bore or the lower edge of the body 1 abutting the ampoule around its neck.

At the bottom of its bore 2 the adaptor top is provided with an opening 4 exposing part of the top of the metal cap with the rubber membrane laid bare. The adaptor top in the shown embodiment is intended for a needle in a hub having an internal thread and consequently it is provided with an outer thread 5 for receiving such a hub with its needle projecting through the opening 4.

At its lower end the body 1 is provided with a flange 6 having triangular knobs 7 intended for cooperation with the syringe using an ampoule carrying this top. The engagement between the knobs 7 and corresponding recesses 21 (see FIGS. 4 and 6–7) in the syringe keeps the top unrotable during screwing on the needle hub.

The outer cylindric contour of the body is shown with opposite flat cuts removing the thread 5 on opposite sides of the cylinder. Such cuts in the cylindric body shape may be made to provide a key for cooperation with a specific syringe, but is in the shown embodiment made for pure moulding related reasons.

FIG. 4 shows schematically the relevant parts of the syringe with an ampoule mounted using an adaptor top according to the invention. The parts of the adaptor top are given the reference numbers of similar parts in the embodiment shown in FIGS. 1–3. A standard ampoule 8 has a neck 9 with a flange 10 against which a rubber membrane 11 is sealingly secured by a metal cap 12 beaded under the flange 10. The bottom of the cup shaped cap 12 has an opening up through which part of the membrane 11 protrudes. The adaptor top is passed with its bore over the cap 12 and pressed down to make the protrusion 3 pass the metal cap and grip under the lower beaded edge of this cap. A needle hub 13 has a depending tubular skirt 20 having an internal thread to be screwed onto the outer thread 5 of the adaptor top with its needle 15 piercing the membrane 11 and projecting into the opening of the neck part of the ampoule. From the drawing it is noticed that the adaptor top is not the type having three protrusions 120° displaced, but has oppositely placed protrusions 3.

The ampoule 8 with the adaptor top is inserted in a syringe housing 14 from the rear end thereof with the adaptor top projecting through an end wall of the syringe housing 14 and with the flange 6 of the adaptor top abutting this end wall. The end wall has recesses 21 to be engaged by the knobs 7 on the flange 6 and the top is this way held unrotably so that the needle hub may be screwed on the top. When screwed on the top the needle hub may be tightened to clamp the end wall of the housing 14 between the flange 6 and the lower edge of the skirt 20. In another not shown embodiment the flange 6 may be omitted and the knobs 7 may be provided on the outer wall of the top and may be received in triangular recesses in the end wall of the syringe housing 14.

In this way the ampoule is held in the syringe in a way making it easy to take out an empty ampoule by unscrewing the needle hub 7 as the ampoule is not wedged in the housing.

FIG. 5 shows another embodiment of an adaptor top mounted on a standard ampoule. Instead of discrete protrusions a ring-shaped protrusion 19 is running at the inner side of the bore. To make it possible to press this top over the metal cap 12 the lower edge carrying the protrusion has either to be very resilient or even to be slotted to enable a deformation allowing the protrusion to pass over the metal cap of the ampoule. Thereby the adaptor top may be too easy to remove unless as shown it is provided with an unresilient locking ring 16 which is kept in position by locking fingers 17. This adaptor top is shown having in its opening an inner thread 18 for receiving a needle hub having an outer thread.

We claim:

1. A pen syringe assembly comprising:

(a) a housing having (i) an inner space and (ii) housing interlocking means which faces the inner space,

(b) an exchangeable standard cartridge, having a neck part with a flange, which is closed by a rubber membrane secured against the flange by a metal cover having an edge beaded behind the flange, and

(c) an adaptor top having (i) a bore with a diameter conforming to the outer diameter of the metal cover of the cartridge for receiving the metal cover of the cartridge therein, (ii) top interlocking means mating the housing interlocking means, and (iii) connecting means adapted to receive an exchangeable needle hub carrying a needle, wherein the adaptor top is mounted on the cartridge which has its neck part pressed into the bore, and wherein the cartridge with the adaptor top is accommodated in the inner space of the housing with the top interlocking means engaging the housing interlocking means.

2. A syringe assembly according to claim 1, wherein the adaptor top is plastic and is provided with a thread coaxial with the bore for receiving a threaded needle hub.

3. A syringe assembly according to claim 2, wherein the housing interlocking means and the adaptor top interlocking means prevent relative rotation between the syringe housing and the adaptor top.

4. A syringe assembly according to claim 3, further comprising a needle assembly comprising a needle hub having a bore with an internal thread, wherein a portion of the adaptor top projects out of a forward end wall of the housing, wherein the adaptor top thread is an exterior thread on such portion, and wherein the needle hub screws over the portion of the adaptor top having the exterior thread to clamp the end wall between the needle hub and part of the adaptor top.

5. A syringe assembly according to claim 1, wherein the bore of the adaptor top includes means for securing the metal cover against axial movement within the bore.

6. A syringe assembly according to claim 5, wherein the means for securing the metal cover within the bore comprise means to engage the metal cover after the metal cover has been inserted a predetermined distance into the bore.

7. A syringe assembly according to claim 6, wherein the means for securing the metal cover against axial movement within the bore comprises at least one protrusion in the bore that grips behind the beaded edge of the metal cover.

8. A syringe assembly according to claim 7, wherein the means for securing the metal cover against axial movement within the bore includes a locking ring.

9. A syringe assembly according to claim 1, wherein the adaptor top interlocking means are knobs at an end of the top, which knobs have triangular cross sections with the apex of the triangle directed towards an end wall of the housing, and wherein the housing interlocking means comprise corresponding triangular depressions in the housing.

10. A syringe assembly according to claim 1, wherein the top is made from a colored plastic to carry information about the content of the cartridge.

11. A syringe assembly according to claim 1, further including a needle assembly engaging the connecting means of the adaptor top.

12. A syringe assembly according to claim 1, wherein the housing interlocking means are located at an end wall of the housing.

13. In combination,

an exchangeable standard cartridge, having a neck part with a flange, which is closed by a rubber membrane secured against the flange by a metal cover having an edge beaded behind the flange, and

an adaptor top having:

a first, axially extending portion having a bore with a diameter conforming to the outer diameter of the metal cover of the cartridge, and an opening for exposing at least a part of the rubber membrane, wherein the metal cover is secured against axial movement within the bore;

a flange portion extending outwardly from the first portion, wherein the first, axially extending portion is adapted to pass through a forward opening in the housing of a syringe, and the flange portion is adapted to secure the adaptor top at a predetermined axial position relative to such syringe housing;

an interlocking member on the flange adapted to fit together with an interlocking means inside a syringe housing; and

connecting means adapted to receive an exchangeable needle hub carrying a needle.

14. The combination of claim 13, wherein the outside surface of the first portion is at least generally circular in cross-section, wherein the flange is an annular flange, and wherein the interlocking member is a projection.

15. The combination of claim 14, wherein the projection is a knob having a triangular cross-section, in which the apex of the triangle faces the direction in which the adaptor top is intended to be passed through a syringe housing.

16. A method of supplying a first medicament and a second medicament, comprising the steps of:

(a) providing the first medicament in a first, exchangeable standard cartridge, such standard cartridge being of the type which has a neck part with a flange closed by a rubber membrane secured against the flange by a metal cover having an edge beaded behind the flange, and which is designed to be inserted into a syringe housing for dispensing the medicament through a needle;

(b) providing the second medicament in a second exchangeable standard cartridge;

(c) providing the first cartridge with a first adaptor top and providing the second cartridge with a second adaptor top, wherein each adaptor top has (i) a bore with a diameter conforming to the outer diameter of the metal cover of the cartridge and means for securing the metal cover against axial movement within the bore, and (ii) top interlocking means adapted to mate with an interlocking means in a syringe housing, wherein the interlocking means of the first adaptor top differs from the interlocking means of the second adaptor top such that a syringe having housing interlocking means that mate with the interlocking means of the first adaptor top would not accept the interlocking means of the second adaptor top; wherein the first and second adaptor tops are mounted on the first and second cartridges, with their neck parts pressed into the bore, thereby to form first and second cartridge assemblies, respectively, and wherein each cartridge assembly includes a connecting means adapted to receive an exchangeable needle hub carrying a needle; and

(d) supply both the first and said second cartridge assemblies for marketing for administration to patients, wherein persons who utilize a syringe that accepts the adaptor top of said first cartridge assembly, for administering the first medicament, are unable to use the second cartridge assembly, and thereby administer the second medicament, using such syringe, thereby preventing an accidental administration of the second medicament.

17. A method according to claim 16, wherein the needle hub connecting means are provided on the respective adaptor tops, and further comprising the step of attaching an exchangeable needle hub on the connecting means.

18. A method of supplying a first medicament and a second medicament, comprising the steps of:

(a) providing the first medicament in a first, exchangeable standard cartridge, such standard cartridge being of the type having a neck part with a flange, which is closed by a rubber membrane secured against the flange by a metal cover having an edge beaded behind the flange, and designed to be inserted into a syringe housing for dispensing the medicament through a needle;

(b) providing the second medicament in a second exchangeable standard cartridge;

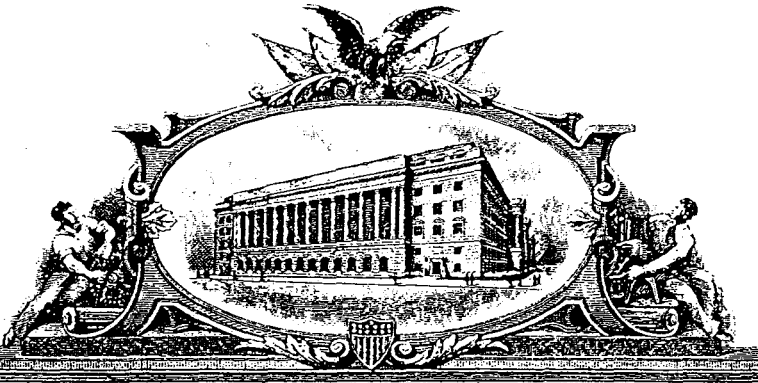
(c) providing the first cartridge with a first adaptor top and providing the second cartridge with a second adaptor top, wherein each adaptor top has a bore with a diameter conforming to the outer diameter of the metal cover of the cartridge and means for securing the metal cover against axial movement within the bore, wherein the first adaptor top has a color which differs from the second adaptor top so as to carry information as to the contents of each cartridge; wherein the respective adaptor top is mounted on a cartridge which has its neck part pressed into the bore, thereby forming first and second cartridge assemblies, respectively, and wherein each cartridge assembly includes a connecting means adapted to receive an exchangeable needle hub carrying a needle; and

(e) supplying both the first and said second cartridge assemblies for marketing for administration to patients, wherein persons intending to administer one type of medicament are able to utilize the color coding on the first and second adaptor types to distinguish between the type of medicament contained in the respective cartridges.

19. A method according to claim 18, wherein the needle hub connecting means are provided on the respective adaptor tops, and further comprising the step of attaching an exchangeable needle hub on the connecting means.

* * * * *

Assignment for ‘027 Patent



THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

April 06, 2006

THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE RECORDS OF THIS OFFICE OF A DOCUMENT RECORDED ON October 9, 1991.

By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office

P. SWAIN
Certifying Officer

27 Rec'd PCT/PTO 0 9 OCT '91

07/768684

A / D

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

3639.504-US

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93 SEP 13 AM 7:49
PATENT & TRADEMARK OFFICE

PCT/DK91/00282	September 20, 1991	September 21, 1990

ADAPTOR TOP

Ib Hansen, Soren Mikkelsen and Frits Frydendal Bonnichsen

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following under 35 U.S.C. 371:
1. [x] This express request to immediately begin national examination procedures (35 U.S.C. 371(f)).
2. [x] The U.S. National Fee (35 U.S.C. 371(c)(1)) and other fees as follows:

CLAIMS	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATION
1	TOTAL CLAIMS	6 -20=	0		$ 0.00
9	INDEPENDENT CLAIMS	1 -3=	0		$ 0.00
	MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+$120.00	$120.00
	BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(4)):				
	[ ] International preliminary examination fee paid to USPTO (37 CFR 1.482)				
	[ ] No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2))				
	[x] Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO			$500	$500.00
	[ ] International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2) to (4)			$50	
	Surcharge of $120. for furnishing the National fee or oath or declaration later than [ ] 20 [ ] 30 mos. from the earliest claimed priority date (37 CFR 1.492(e)).				$
			TOTAL OF ABOVE CALCULATIONS		= $620.00
	Reduction by 1/2 for filing by small entity, if applicable. Affidavit must be filed also. (Note 37 CFR 1.9, 1.27, 1.28.)				
				SUBTOTAL	+
	Processing fee of $30. for furnishing the English Translation later than [ ] 20 [ ] 30 mos. from the earliest claimed priority date (37 CFR 1.492(f)).				
			TOTAL NATIONAL FEE		$620.00
	Fee for recording the enclosed assignment (37 CFR 1.21(h)).				+
			TOTAL FEES CHARGED		$620.00

a. [ ] A check in the amount of $_____ to cover the above fees is enclosed.
b. [X] Please charge my Deposit Account No. 14-1447 in the amount of $620.00 to cover the above fees. A duplicate copy of this sheet is enclosed.
c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-1447. A duplicate of this sheet is enclosed.

93301964

3639.504-US

3. A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [ ] is transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
   c. [X] has been transmitted by the International Bureau.
4. [ ] A translation of the International Application into English (35 U.S.C. 371(c)(2)).
5. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] have been transmitted by the International Bureau.
6. [ ] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
7. [X] An oath or declaration of the inventor (35 U.S.C. 371(c)(4)).
8. [ ] A translation of the Annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Other document(s) or information included:

9. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
10. [X] An assignment document for recording.
    Please mail the recorded assignment document to:
    a. [ ] the person whose signature, name & address appears at the bottom of this page.
    b. [ ] the following:

REEL 6226 FRAME 113

11. The above checked items are being transmitted
    a. [X] before the 18th month publication.
    b. [ ] after publication and the Article 20 communication but before 20 months from the priority date.
    c. [ ] after 20 months but before 22 months (surcharge and/or processing fee included).
    d. [ ] after 22 months (surcharge and/or processing fee included).
       Note: Petition to revive (37 CFR 1.137(a) or (b)) is necessary if 35 U.S.C. 371 requirements submitted after 22 months and no proper demand for International Preliminary Examination was made by 19 months from the earliest claimed priority date.
    e. [ ] by 30 months and a proper demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
    f. [ ] after 30 months but before 32 months and a proper demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date (surcharge and/or processing fee included).
    g. [ ] after 32 months (surcharge and/or processing fee included).
       Note: Petition to revive (37 CFR 1.137(a) or (b)) is necessary if 35 U.S.C. 371 requirements submitted after 32 months and a proper demand for International Preliminary Examination was made by 19 months from the earliest claimed priority date.
12. At the time of transmittal, the time limit for amending claims under Article 19
    a. [ ] has expired and no amendments were made.
    b. [ ] has not yet expired.
13. [ ] Certain requirements under 35 U.S.C. 371 were previously submitted by the applicant on _____ (date), namely:

Elias J. Lambiris
NAME

Novo Nordisk of North America, Inc.

405 Lexington Avenue, Suite 6200
ADDRESS

New York, New York 10017

(212) 867-0123
TELEPHONE

Elias J. Lambiris
SIGNATURE

33,728
REGISTRATION NUMBER

Form PTO-1390 (Rev. 3-90)

Docket No. 3639.504-US PATENT

ASSIGNMENT OF APPLICATION FOR PATENT

WHEREAS:

Ib HANSEN, a citizen of Denmark, residing at Oerslevvej 2, DK-2730 Herlev, Denmark
Søren MIKKELSEN, a citizen of Denmark, residing at Skovlyporten, Blok 6, nr. 3, DK-2840 Holte, Denmark
Frits Frydendal, BONNICHSEN, a citizen of Denmark, residing at Hoejdevej 31, DK-3540 Lynge, Denmark

(hereinafter ASSIGNORS), have made a discovery or invention entitled:

ADAPTOR TOP

for which application of Letters Patent of the United States has been filed on to be assigned under Serial No. to be assigned and

WHEREAS:

Novo Nordisk A/S, a corporation organized under the law of Denmark, located at Novo Alle, DK-2880, Bagsvaerd, Denmark (hereinafter ASSIGNEE), is desirous of acquiring the entire interest in, to and under said invention and in, to and under Letters Patent or similar legal protection to be obtained therefor in the United States and in any and all foreign countries.

NOW, THEREFORE, in consideration of the payment by ASSIGNEE to ASSIGNORS of the sum of one dollar ($1) or the equivalent thereof, the receipt of which is hereby acknowledged, and for other good and valuable consideration, ASSIGNORS hereby sell, assign and transfer to ASSIGNEE, its successors, legal representatives and assigns, the full and exclusive rights, titles and interests to said discovery or invention in the United States and its territorial possessions and in all foreign countries and to all Letters Patent or similar legal protection in the United States and its territorial possessions and in any and all foreign countries to be obtained for said invention by said application or any continuation, division, renewal, substitute or reissue thereof or any legal equivalent thereof in a foreign country for the full term or terms for which the same may be granted.

SAID ASSIGNORS hereby authorize and request the Commissioner of Patents and Trademarks of the United States of America and any Official of any country or countries foreign to the United States of America whose duty it is to issue Letters Patent on applications as aforesaid, to issue all such Letters Patent

for said discovery or invention to the ASSIGNEE, as assignee of the entire right, title and interest in, to and under the same, for the sole use and behalf of the ASSIGNEE, its successors, legal representatives and assigns, in accordance with the terms of this instrument.

SAID ASSIGNORS hereby covenant that we have full right to convey the entire right, title and interest herein sold, assigned, transferred and set over.

AND SAID ASSIGNORS hereby further covenant and agree that the ASSIGNEE, its successors, legal representatives, and assigns, may apply for foreign Letters Patent on said discovery or invention and claim the benefits of the International Convention, and that we will, at any time, when called upon to do so by the ASSIGNEE, its successors, legal representatives, or assigns, communicate to the ASSIGNEE, its successors, legal representatives, or assigns, as the case may be, any facts known to us respecting said discovery or invention, and execute and deliver any and all lawful papers that may be necessary or desirable to perfect the title to the said discovery or invention, the said applications and the said Letters Patent in the ASSIGNEE, its successors, legal representatives and assigns, and that if reissues of the said Letters Patent or disclaimers relating thereto, or divisions, continuations, or refilings of the said applications, or any thereof, shall hereafter be desired by the ASSIGNEE, its successors, legal representatives or assigns, we will, at any time, when called upon to do so by the ASSIGNEE, its successors, legal representatives, or assigns, sign all lawful papers, make all rightful oaths, execute and deliver all such disclaimers and all divisional, continuation and reissue applications so desired, and do all lawful acts requisite for the application for such reissues and the procuring thereof and for the filing of such disclaimers and such applications, and generally do everything possible to aid the ASSIGNEE, its successors, legal representatives and assigns, to obtain and enforce proper patent protection for said invention or discovery in all countries, all without further compensation but at the expense of the ASSIGNEE, its successors, legal representatives and assigns.

Date: 1991.10.01 — Ib Hansen

Date: 911003 — Søren Mikkelsen

Date: 911009 — Frits Frydendal Bonnichsen

RECORDED
PATENT AND TRADEMARK
OFFICE
OCT -9 1991

REEL 6226 FRM 115

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

CERTAIN INSULIN DELIVERY DEVICES, INCLUDING CARTRIDGES HAVING ADAPTORS TOPS AND COMPONENTS THEREOF

Inv. No. 337-TA-572

Order No. 6: INITIAL DETERMINATION Terminating the Investigation Based on Withdrawal of the Complaint

By publication of a notice in the *Federal Register* on June 9, 2006, pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, the Commission instituted this investigation to determine:

> [W]hether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain insulin delivery devices, including cartridges having adaptor tops, or components thereof, by reason of infringement of claims 1-3, 5-7, 11, 18, or 19 of U.S. Patent 5,693,027, and whether an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337.

71 Fed. Reg. 33484 (2006).

The complainants are: Novo Nordisk A/S of Denmark; Novo Nordisk Inc. of Princeton, New Jersey; and Novo Nordisk Pharmaceuticals Industries, Inc. of North Carolina. The Commission named as the respondents: Sanofi-Aventis Deutschland GmbH of Germany; Sanofi-Aventis of France; and Aventis Pharmaceuticals, Inc. of Bridgewater, New Jersey. The Commission Investigative Staff is also a party in this investigation. *Id.*

On October 5, 2006, pursuant to 19 C.F.R. 210.21(a)(1), complainants filed their "Motion to Withdraw the Complaint and Terminate the Investigation As to All Parties." Motion Docket No. 572-4.

On October 13, 2006, respondents filed their response to the motion. Respondents argue that although they do not oppose withdrawal of the complaint, complainants knowingly made baseless allegations against respondents and therefore the investigation should be terminated with prejudice. Further, it is argued that complainants should be required to pay litigation fees to respondents.

On October 16, 2006, the Commission Investigative Staff filed a response in support of complainants' motion to withdraw the complaint.

On October 17, 2006, complainants filed a motion for leave to reply. Motion Docket No. 572-6. Motion No. 572-6 for leave to reply is GRANTED.

The Commission's Rules provide that a complainant may withdraw a complaint as a matter or right before the Commission votes on whether to institute an investigation. 19 C.F.R. § 210.10(a)(5)(i). Thereafter, a complainant may file a motion to withdraw the complaint before issuance of the initial determination on violation of section 337, and the Administrative Law Judge may grant such a motion upon such terms and conditions as he deems proper. 19 C.F.R. § 210.21(a). The Commission has held that in the absence of extraordinary circumstances, termination of an investigation will be readily granted during its prehearing stage. *See Certain Ultrafiltration Systems and Components Thereof, Including Ultrafiltration Membranes*, Inv. No. 337-TA-107, Commission Action and Order at 2 (Mar. 11, 1982).

In this instance, respondents request that termination be made with prejudice. However,

the Commission has held that termination with prejudice is not available as a matter of policy based on the Commission's interpretations of the statute and its Rules of Practice and Procedure. *See, e.g., Certain Bar Clamps, Bar Clamp Pads, and Related Packaging, Display, and Other Materials,* Inv. No. 337-TA-429, Commission Opinion at 6 (Feb. 13, 2001). Respondents' other arguments concerning the alleged improper basis for filing the complaint are the subject of respondents' Motion No. 569-5 for sanctions, which was denied in Order No. 5. Nevertheless, no party argues that extraordinary circumstances warrant denial of complainants' motion to withdraw the complaint. Indeed, all parties consent to termination of the investigation.

Accordingly, complainants' Motion No. 572-4 to terminate this investigation based on withdrawal of the complaint is GRANTED.

Pursuant to 19 C.F.R. § 210.42(h), this initial determination shall become the determination of the Commission unless a party files a petition for review of the initial determination pursuant to 19 C.F.R. § 210.43(a), or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the initial determination or certain issues contained herein.

Sidney Harris
Administrative Law Judge

Issued: January 29, 2007

CERTAIN INSULIN DELIVERY DEVICES, INCLUDING CARTRIDGES HAVING ADAPTORS TOPS AND COMPONENTS THEREOF

INV. NO. 337-TA-572

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **Order (ID)** has been served on upon Juan Cockburn, Esq. and upon the following parties via first class mail, and air mail where necessary on **January 31, 2007**.

Marilyn R. Abbott, Secretary
U.S. International Trade Commission
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CERTAIN INSULIN DELIVERY DEVICES, INCLUDING CARTRIDGES HAVING ADAPTORS TOPS AND COMPONENTS THEREOF

INV. NO. 337-TA-572

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